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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/612,285	07/03/2003	Richard Derek Iggo	604-689	5824	
	23117 7590 08/23/2007 NIXON & VANDERHYE, PC			EXAMINER	
901 NORTH G	LEBE ROAD, 11TH F	PRIEBE, SCOTT DAVID			
ARLINGTON,	VA 22203		ART UNIT	PAPER NUMBER	
			1633		
			<u></u>		
			MAIL DATE	DELIVERY MODE	
			08/23/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/612,285	IGGO ET AL.			
Office Action Summary	Examiner	Art Unit			
	Scott D. Priebe, Ph.D.	1633			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on 03 Ju	<u>ıly 2007</u> .				
2a)⊠ This action is <b>FINAL</b> . 2b)☐ This	This action is <b>FINAL</b> . 2b) This action is non-final.				
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4) ☐ Claim(s) 1-3,5-11,21 and 22 is/are pending in to 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) is/are allowed.  6) ☐ Claim(s) 1-3,5-11,21 and 22 is/are rejected.  7) ☐ Claim(s) is/are objected to.  8) ☐ Claim(s) are subject to restriction and/or	vn from consideration.				
Application Papers					
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acce Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex	epted or b) objected to by the liderawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)					
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ate Patent Application			

Art Unit: 1633

## **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

# Oath/Declaration

The oath or declaration remains defective for the reasons of record set forth in the Office action of 1/3/07. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 602.

Applicant has indicated in the reply of 7/3/07 that a corrected declaration will be submitted.

# Claim Rejections - 35 USC § 112

Claims 1-3, 5-11, 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the endogenous left hand inverted terminal repeat (ITR) transcription factor binding sites" in lines 7-8. There is insufficient antecedent basis for this limitation in the claim. Deletion of "the" from this phrase would be remedial.

Art Unit: 1633

Claims 1-3, 5-11, 21 and 22 remain rejected under 35 U.S.C. 112, second paragraph, for the reasons of record set forth in the Office actions of 3/7/06 and 1/3/07 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the number of human or animal transcription factor binding sites to those inserted as substations in ... E1A open reading frame" in lines 13-14.

There is insufficient antecedent basis for this limitation in the claim. The claim does not indicate that binding sites are "inserted with the E1A open reading frame".

Claim 1 recites the limitation "the adenovirus E1A open reading frame" in line 5. There is insufficient antecedent basis for these limitations in the claim. Insertion --of the wild type adenoviral DNA sequence-- following "frame" would provide the antecedent basis.

Claim 8 recites the limitations "the E4 promoter" and "the E1A enhancer" in line 2.

There is insufficient antecedent basis for these limitations in the claim.

Applicant's arguments filed 7/3/07 have been fully considered but they are not persuasive. Applicant indicates that the amendments have overcome the previous grounds of rejection. In response, the amendments have overcome some, but not all, of the grounds of rejection.

## Claim Rejections - 35 USC § 102

Claims 1, 3, 7, 9-11, 21, and 22 remain rejected under 35 U.S.C. 102(b) as being anticipated by Iggo et al., WO 00/56909 for the reasons of record set forth in the Office action of 7/11/05.

Application/Control Number: 10/612,285

Art Unit: 1633

Applicant's arguments filed 7/3/07 have been fully considered but they are not persuasive. Applicant merely asserts that the claimed invention is not suggested by Iggo and E1A is not mechanistically "directly" involved in viral replication. In response, regulation is part of the mechanism. Also, Iggo explicitly teaches modifying the E1A and E1B promoters with the transcription factor binding sites, which not excluded by the amended claims.

# Claim Rejections - 35 USC § 103

Claims 1, 3, 7, 9-11, 21, and 22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al., US 6,197,293 in view of Iggo et al., WO 00/56909.

Applicant's arguments filed 7/3/07 have been fully considered but they are not persuasive. Applicant states that "[N]either of the references discloses or suggests E1B control with wild type E2 or E3 and relocation of packaging signal". Without responding to the accuracy of this statement, the claims do not require such limitations, and the relevance of the statement is therefore unclear.

## Double Patenting

Claims 1-3, 5-11, 21, and 22 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 7, 9, 11-16, 19, 20, and 25-38 of copending Application No. 10/433,681 for the reasons of record set forth in the Office action of 7/11/05. The claims as amended in the instant and copending applications are directed to the same disclosed embodiments, although the claims do not precisely match in scope.

Application/Control Number: 10/612,285

Art Unit: 1633

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant has acknowledged the rejection but has declined to address it until prosecution has otherwise been completed in the two applications. Applicant is reminded of recent changes to procedures involving provisional obviousness-type double patenting rejections involving copending applications, see MPEP 804, subsection I.B.1. In a situation like this one, a proper provisional rejection in the junior application may not be withdrawn so long as the senior application is pending, even if junior application is otherwise in condition for allowance, but the senior application is not.

## **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Application/Control Number: 10/612,285

Art Unit: 1633

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Scott D. Priebe/

Page 6

Scott D. Priebe, Ph.D. Primary Examiner Art Unit 1633